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(54) **Safety needle containers.**

(57) A safety adapter has a base 2 comprised of a first section 2a which mates with the hub 66 of a needle 68 and a second section 2B which mates with the snout of a syringe 60. A housing 14 is flexibly connected to a shoulder 8 extending from the first section 2a, by means of a flexible web 12. After injection, or removal of a blood sample, the housing 14 is pivoted to envelope the needle 68 completely. The needle 68 is locked within the housing 14 by at least one integral hook 40, 42, the needle 68 can not thereafter be exposed and the danger of accidental pricking by the needle 68 is eliminated. The dead space volume at the junction where the needle 68 is connected to the syringe 60 can be reduced by means of a conical extension 50 within the second section 2B.

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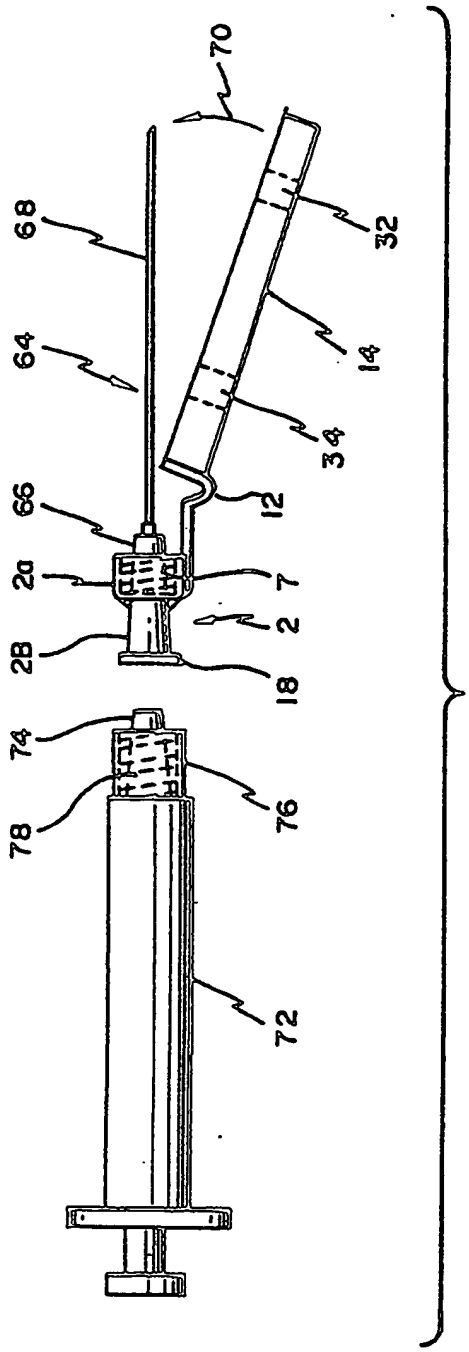

FIG. 4

This invention relates to a safety device for use with a needle.

In handling a hypodermic needle, there is always a chance that the user, or persons in the proximity of the needle, may be exposed to accidental pricking thereby. And in view of the current crop of infectious diseases, particularly the as yet incurable Acquired Immune Deficiency Syndrome (AIDS), an urgent need exists to provide a safety device for preventing accidental pricking by a needle, especially one that has been used and is therefore contaminated.

There are in the prior art a number of safety devices for guarding a needle assembly, or more precisely its needle or cannula, so that its sharp end will not be exposed. For example, Sponsel US patent 1,779,451 discloses a syringe that has a needle guard pivotable at a point about the syringe casing for guarding the needle. Scislowicz US patent 3,323,523 discloses a sheath formed of two portions that can pivot about respective hinges to cover a needle. Moreover, the sheath may be locked by having a sleeve slid thereover. Hall US patent 3,658,061 discloses a catheter needle guard unit that may be pivoted to snap over the needle. The sheath, once snapped, may be unsnapped since it is not locked onto the needle. Smith, Jr. US patent 4,643,722 discloses a hypodermic needle assembly that has a closure having an elongated slot which enables the closure to be either removed from or inserted toward the hypodermic needle. The Smith device requires two-handed operation. Furthermore, no locking means is disclosed. Nelson et al. US patent 4,659,330, discloses a needle protective cap which is slidable, by means of a clip, along the body of the syringe. The needle cover, however, may be completely removed from the needle.

Additional slidable needle protectors are disclosed in Spencer US patents 4,702,738 and 4,723,943 wherein a protective sheath is shown to be slidable along a syringe body. Further needle covers that are slidable along a syringe body are disclosed in Choksi US patent 4,737,144 and Schnieder US patent 4,743,233. Some other example devices having protective sheaths for needles include Laico et al. US patent 4,804,372; Poncy US patent 4,816,022; Schramm US patent 4,826,491; Poncy US patent 4,842,587; Carrell et al. US patent 4,846,796; Romano US patent 4,850,968; Bayless US patent 4,850,977; Zerbst et al. US patent 4,850,994; Cree US patent 4,850,996; Jordan et al. US patent 4,858,607; Bayless US patent 4,863,434 and Haber US patent 4,892,107. As is readily apparent, all of these devices having covers that are slidable along the length of the syringe body require two-handed operation.

Another type of prior art needle protective device involves the pivoting of a sheath to cover the needle. Some prior art examples of this type of device include Norelli US patent 4,820,277 wherein a pair of jaws are pivotable and lockable over a needle. As is readily apparent, however, the Norelli cover also requires two-handed operation. Glazier US patent 4,883,469 discloses a guard assembly that is coupled to a sheath by a fastener and is rotatable about a hinge to snap onto the needle. The sheath, along with the pivotable guard, has to be preassembled with the needle for a specific type of syringe. Schoenberg US patent 4,888,001 discloses a longitudinal shank having two flat wings which are pivotable to enclose the sharp distal end of the needle. None of these prior art devices apparently discloses the permanent retention of the needle by the protective sheath once the protective sheath has been pivoted to enclose the needle.

There are prior art safety devices that teach the permanent retention of a needle within the housing once it has been enclosed thereby. Landis US patent 4,664,259 is one such which disloses a needle assembly that includes a pivotable housing having therein a hook to retain the needle within the housing after the housing has been pivoted to enclose the needle. The Landis device, however, comes in a unitary package, inasmuch as the needle is integrated into the base, which in turn has connected thereto the pivotable housing. In Unger US patent 4,872,552, there is also disclosed a pivotable housing integrated into a needle. In an alternative embodiment, the Unger housing has to be threaded to a specific type of a needle housing hub. To lock the housing permanently to the needle, a plug has to be pushed from the top of the housing longitudinally into the housing until the tip of the needle rests within the plug.

Even with the '259 and '552 devices, inasmuch as there is available in the market a number of different types of needles and syringes, there still remains a need to have a universal safety device that is adaptable to be used with the different types of needles and syringes. Moreoever, it is imperative that such safety devices are suitable for single-handed operation, as for example during emergency room situations where a user may have only one hand free.

Moreover, it has been found that there is often a large unused and therefore wasteful volume of space at the junction where the syringe and needle are joined which has to be filled with blood drawn from, or fluid to be injected into, a patient.

It is an object of the present invention to provide a safety device for use with a needle that avoids these disadvantages.

According to one aspect of the present invention there is provided a safety device of the above specified kind, characterised in that the device comprises a base having a first section adapted to mate with the needle and a second section adapted to mate with a syringe, and a housing flexibly connected to the base and pivotable to a position substantially in alignment

with the needle to envelope the needle, and that the housing includes locking means to fixedly retain the needle within the housing once the housing has been pivoted into position.

The safety device preferably has an elongate slot through which the needle passes when the housing is pivoted into position. The locking means may comprise at least one hook for securely retaining the needle within the housing. The or each hook may be integral with the housing.

The base preferably includes a rigid shoulder extending therefrom. The housing may be coupled to the base by a flexible web. The housing is preferably coupled to the substantially rigid shoulder by the flexible web.

The first section preferably includes a protrusion and a threaded collar surrounding the protrusion to effect mating of the protrusion with the needle hub.

The second section preferably has a bore extending therethrough, a part at least of the bore being tapered to mate with the ejection end of the syringe. The second section may include an extension adapted to mate with an internally-threaded collar that surrounds the ejection end of the syringe.

The first section preferably has a through bore substantially the size of the bore of the needle, the second section preferably has a conical extension projecting away from the first section having a through bore substantially equal to that of the first section, the respective through bores of the first section and the conical extension effecting one continous through bore in the base; and that the conical extension is arranged to be inserted into the ejection end of the syringe when the second section is mated therewith, said conical extension substantially reducing the volume of space through which fluid transits between the syringe and the needle.

A safety needle adapter in accordance with the present invention, will now be described by way of example, with reference to the accompanying drawings, in which:

Figure 1A is a side view of a first embodiment of the present invention safety adapter;

Figure 1B is a plan view of the Figure 1A embodiment;

Figure 1C is a cross-sectional view of section A-A noted in Figure 1B;

Figure 2A is a semi-cross sectional view of another embodiment of the safety adapter of the present invention;

Figure 2B is a plan view of the Figure 2 embodiment;

Figure 2C is a cross-sectional view shown along cut A-A in Figure 2B;

Figure 3 is an overall view of the safety adapter of the present invention being used with a luer slip type syringe: and

Figure 4 is an overall view of the safety adapter of the present invention being used with a luer lock type syringe.

With reference to Figure 1A, there is shown a safety needle adapter having a base 2 with a first section 2a and a second section 2b. Both sections 2a and 2b are integral of one piece moulded base 2.

Section 2a includes a central protrusion 4, conventionally known as a male luer. Surrounding protrusion 4 is an annular collar 6, extending from approximately the midsection of base 2. Collar 6, although not shown as such in Figure 1A, in practice, is internally threaded 7, as shown in Figure 2A. Extending from a portion of collar 6 is a substantially rigid shoulder member 8. Connected to the distal end 10 of shoulder member 8, by way of a living hinge or flexible web 12, is a housing 14.

Section 2b extends approximately from the midsection of base 2 away from collar 6, as a hub or extension 16. At the distal end of hub 16 is, for this embodiment, a circumferential extension 18, extending orthogonally to the longitudinal length of base 2, for mating with the internal threads of a syringe. It should be appreciated that instead of a ring-like extension, 18 may actually be comprised of a plurality of singular extensions. There is formed at the base of hub 16 an opening 20 which extends in a decreasingly tapered fashion along dotted lines 22a and 22b to the top of protrusion 4 to meet with an opening 24. Conventionally, hub 16 may also be considered as the female luer portion of the adapter of the present invention.

By connecting housing 14 via living hinge 12 to shoulder member 8, housing 14 is pivotable about distal end 10 of shoulder member 8, such that it comes into an alignment position about the longitudinal axis of the needle or cannula (which is also the longitudinal axis of base 2) of a needle assembly, as shown and to be discussed in Figures 3 and 4. There is shown in greater detail in Figure 1B an elongated slot 26 running from base 28 of housing 14 to tip 30 thereof. Tip 30 for this embodiment is solid, but may be hollow for other embodiments. The length of housing 14 is such that it may be used for the longest or shortest, as well as any length in between, needle available in the market.

As shown in Figure 1B, there is an opening 32 located near tip 30 and another opening 34 located closer to base 28 of housing 14. With reference also to Figure 1C, it can be seen that slot 26 is bounded by sides 36a and 36b, running substantially in parallel along the length of housing 14, and a base 38. At the center of respective openings 32 and 34 there is integral with the housing 14 corresponding hook-like retaining mechanisms 40 and 42. At best shown in Figure 1C, each of the retaining mechanisms 40 and 42 has a substantially rigid finger 40a extending in a downward slope fashion from the apex of extension 40b, molded to base 38. It should be appreciated that,

although substantially rigid, finger 40a may be biased by the cannula of a needle assembly toward extension 40b until the cannula is past tip 40T thereof, at which time finger 40a flexes back into the position shown in Figure 1C, thereby permanently retaining the cannula within the space defined between finger 40a and extension 40B to prevent the cannula from moving relative to housing 14.

Retainer mechanism 42 is the same as retainer mechanism 40 except, as shown in Figure 1B, its finger portion 42B slopes downward toward side 36B of housing 14. In contrast, finger 40a of retaining mechanism 40 is shown to be sloping downward toward side 36a in the housing. By thus transposing the finger portions of the respective retaining mechanisms, it becomes more difficult for the cannula of the needle assembly to be forcibly removed from the housing, were the cannula being retained by both retaining mechanisms.

To provide strength for the housing, a plurality of ribs 38 is provided along the length of housing 14. Likewise, to provide strength to base 2, a number of buttress ribs 40 slanting upward from hub 16 to base 6B of annular collar 6 is used. These buttress ribs provide rigidity and strength to base 2 such that the latter would not crack even if it were subjected to undue bending moment at base 6B.

A second embodiment of the safety adapter of the present invention is illustrated in Figures 2A, 2B and 2C. For these figures, components which are the same as the components shown in Figure 1A, 1B and 1C, or perform essentially the same functions, are labelled the same.

Like the first embodiment, the Figure 2 embodiment also has a base 2 connected, by way of a shoulder member 8 and a flexible web or living hinge 12, to a housing 14. This embodiment, however, is directed to substantially reducing the volume of space through which a fluid, be it blood or medicament, transits between the syringe and the needle, as for example when blood is being drawn from a patient to the syringe or when a medicament in the syringe is being intravenously fed to the patient via the needle.

To achieve this end, the embodiment of Figure 2A has incorporated into base 2, particularly at section 2B, a conical extension (i.e., a snout or male luer) 50 extending from approximately base 6B to beyond the plane of hole 20 at the base of the adapter. Furthermore, instead of having a through bore such as 23 shown in Figure 1 extending from top hole 24 to bottom hole 20 and confined by sidewalls 22a and 22B and therefore having a substantial amount of dead space, the Figure 2A embodiment now has a through bore 52 running continuously from top 4T of male luer 4 at opening 54 to the distal end of conical extension 50, at opening 56. The diameter of through bore 52 is to be manufactured to substantially correspond to the typical bore of a typical needle (cannula) of a needle assembly so that fluid transiting between openings 54 and 56 would flow directly into the bore of the cannula, without having to fill up unnecessary dead space such as shown in Figure 1A.

The inventor has found that this elimination of dead space, in addition to being attractive to a clinician, in actuality, has the important advantage of not requiring the withdrawal of a larger amount of blood than is necessary, as is done conventionally. To elaborate, ordinarily, for an infant, to withdraw an amount of blood more than is necessary (for example $\frac{1}{2}$ cc) for the requisite tests would be traumatic. Yet, conventionally, a lot more blood than is necessary is in fact withdrawn from the infant, in view of the large amount of dead space between the syringe and the needle, such as examplified by through bore 23 in Figure 1A.

With the embodiment shown in Figure 2A, however, inasmuch as the through bore through which fluid transits has been reduced by conical extension 50, acting effectively as a male extension within female luer 16 at section 2B of base 2, only a minimal necessary amount of blood needs to be drawn. It should be appreciated that the length of conical extension 50 in section 2B, and the length of male luer 4 in section 2a, may be longer or shorter than the respective lengths illustrated in Figure 2B. Likewise, the length of shoulder member 8 may be lengthened or shortened, so long as it enables housing 14, when pivoted to align along and about the longitudinal axis of the cannula, to be clear of the hub of the assembly to which the cannula is attached.

In operation, with reference to Figures 3 and 4, it can be seen that either embodiment of the safety adapter of the instant invention may be mated to a luer slip syringe 60, shown in Figure 3, that has as its ejection end a male luer 62. For the Figure 3 illustration, assuming that the safety adapter embodiment shown in Figure 1A is used, the user needs only to slip-fittedly insert male luer 62 into female luer 2b of base 2 for mating. Needle assembly 64, in the meanwhile, is threaded, by means of its hub 66, into annular collar 6. The female luer portion of hub 66 of needle assembly 64 is therefore mated to male luer 4 of base 2, best shown in Figure 1A. Cannula 68 of needle assembly 64, after use, can be prevented from being exposed and accidentally pricking a person by pivoting housing 14, via living hinge 12 following directional arrow 70, to envelope cannula 68.

As should be readily apparent, when housing 14 is pivoted to align along the longitudinal axis of cannula 68, retaining mechanisms 40 and 42 (see Figures 1A and 1B), upon closing of housing 14 onto cannula 68, will securely retain the housing so that there is no relative movement between housing and cannula. It should further be appeciated that, as the length of cannula 68 varies, the fact that there are a plurality of retaining mechanisms integral of housing

14 ensures that the cannula would be retained therein. Alternatively, it should further be appreciated that in place of a plurality of retaining mechanisms, only one retaining mechanism, appropriately positioned somewhere along the length of housing 14, may be used. The relative positioning of the retaining mechanisms along housing 14 is determined, of course, to a great extent, by the envisioned length of the cannula to be used.

For the Figure 3 illustration, if the embodiment of the safety adapter of Figure 2A is to be used in place of that shown in Figure 1A, the same slip-fit mating of male luer 62 and female luer 2B discussed earlier remains true. But in addition to that, the conical extension (male luer) 50 within female luer 2B of base 2 (see Figure 2A) is now inserted through hole 73 into male luer 62 of syringe 60. And inasmuch as through bore 52 (see Figure 2A) had substantially the same diameter as the bore of cannula 68 and thus in effect provides a direct path from syringe 60 into hub 66 of needle assembly 64, the volume of space through which a fluid transits between syringe 60 and cannula 68 is substantially reduced. In other words, the dead space volume in a conventional connection between the hub of a needle assembly and the male luer of a syringe is substantially reduced.

In Figure 4, there is shown a luer lock type syringe 72 which has an internally threaded collar 76 surrounding its male luer 74. The mating of hub 66 of needle assembly 64 to section 2a of base 2 is as was discussed with reference to Figure 3 and therefore will not be further discussed herein. As for the mating of section 2B to male luer 74, with the addition of annular collar 76, extension 18 at the distal end of section 2b (see Figure 2A) is now used to threadedly mate with thread 78 at the inner circumference of collar 76. Male luer 74 of course will remain slip-fittedly mated with section 2B, if the safety adapter shown in Figure 1A is used. If, instead, the safety adapter shown in Figure 2A is used, then in addition to slip fitting along sides 22a and 22B (see Figure 2A) of section 2b, the interior of male luer 74 will also be mated with conical extension 50 so that dead space volume will be reduced.

Inasmuch as the present invention is subject to many variations, modifications and changes in detail, it is intended that all matter described throughout this specification and shown in the accompanying drawings be interpreted as illustrative only and not in a limiting sense. Accordingly, it is intended that the invention be limited by the spirit and scope of the hereto appended claims.

Claims

1. A safety device for use with a needle, characterised in that the device comprises: a base (2) having a first section (2a) adapted to mate with the needle (68) and a second section (2b) adapted to mate with a syringe (60, 72), and a housing (14) flexibly connected to the base (2) and pivotable to a position substantially in alignment with the needle to envelope the needle, and that the housing (14) includes locking means (40, 42) to fixedly retain the needle (68) within the housing (14) once the housing (14) has been pivoted into position.

2. A safety device according to Claim 1, characterised in that the housing (14) has an elongate slot (26) through which the needle (68) passes when the housing (14) is pivoted into position.

3. A safety device according to Claim 1 or 2, characterised in that the locking means comprises at least one hook (40, 42) for securely retaining the needle (68) within the housing (14).

4. A safety device according to Claim 3, characterised in that the or each hook (40, 42) is integral with the housing (14).

5. A safety device according to any one of the preceding claims, characterised in that the base (2) includes a rigid shoulder (8) extending therefrom.

6. A safety device according to any one of the preceding claims, characterised in that the housing (14) is coupled to the base by a flexible web (12).

7. A safety device according to Claims 5 and 6, characterised in that the housing (14) is coupled to the rigid shoulder (8) by the flexible web (12).

8. A safety device according to any one of the preceding claims, characterised in that the first section (2a) includes a protrusion (4) and a threaded collar (6) surrounding the protrusion (14) to effect mating of the protrusion (4) with the needle hub (66).

9. A safety device according to any one of the preceding claims, characterised in that the second section (2b) has a bore (23) extending therethrough, and that a part at least of the bore (23) is tapered to mate with the ejection end of the syringe (60).

10. A safety device according to any one of the preceding claims, characterised in that the second section (2B) includes an extension (18) adapted to mate with an internally-threaded collar (76) that surrounds the ejection end of the syringe (72).

11. A safety device according to any one of the preceding claims, characterised in that the first sec-

tion (2a) has a through bore (52) substantially the size of the bore of the needle (68), that the second section (2B) has a conical extension (50) projecting away from the first section (2a) having a through bore (52) substantially equal to that of the first section (2a), the respective through bores (52) of the first section (2a) and the conical extension (50) effecting one continous through bore in the base (2); and that the conical extension (50) is shaped for insertion into the ejection end (74) of the syringe (72) when the second section (2B) is mated therewith, the conical extension (50) substantially reducing the volume of space through which fluid transits between the syringe (72) and the needle (68).

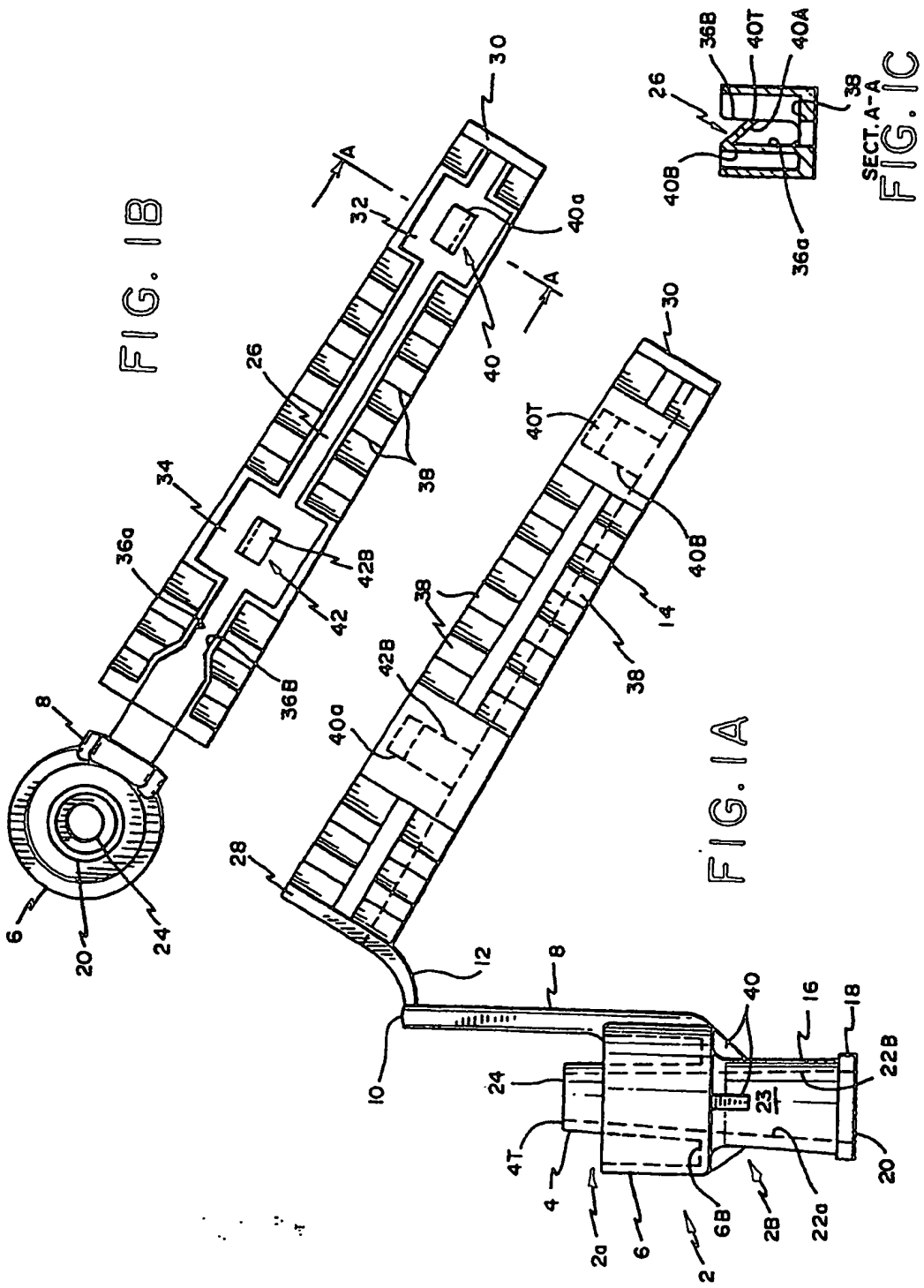
FIG. 1B
FIG. 1A
FIG. 1C
SECT. A-A
30
32
A
40a
40
26
38
34
36a
42B
42
36B
8
6
20
24
28
40T
40B
14
12
10
16
18
22B
23
4T
4
2a
6
6B
2
28
22a

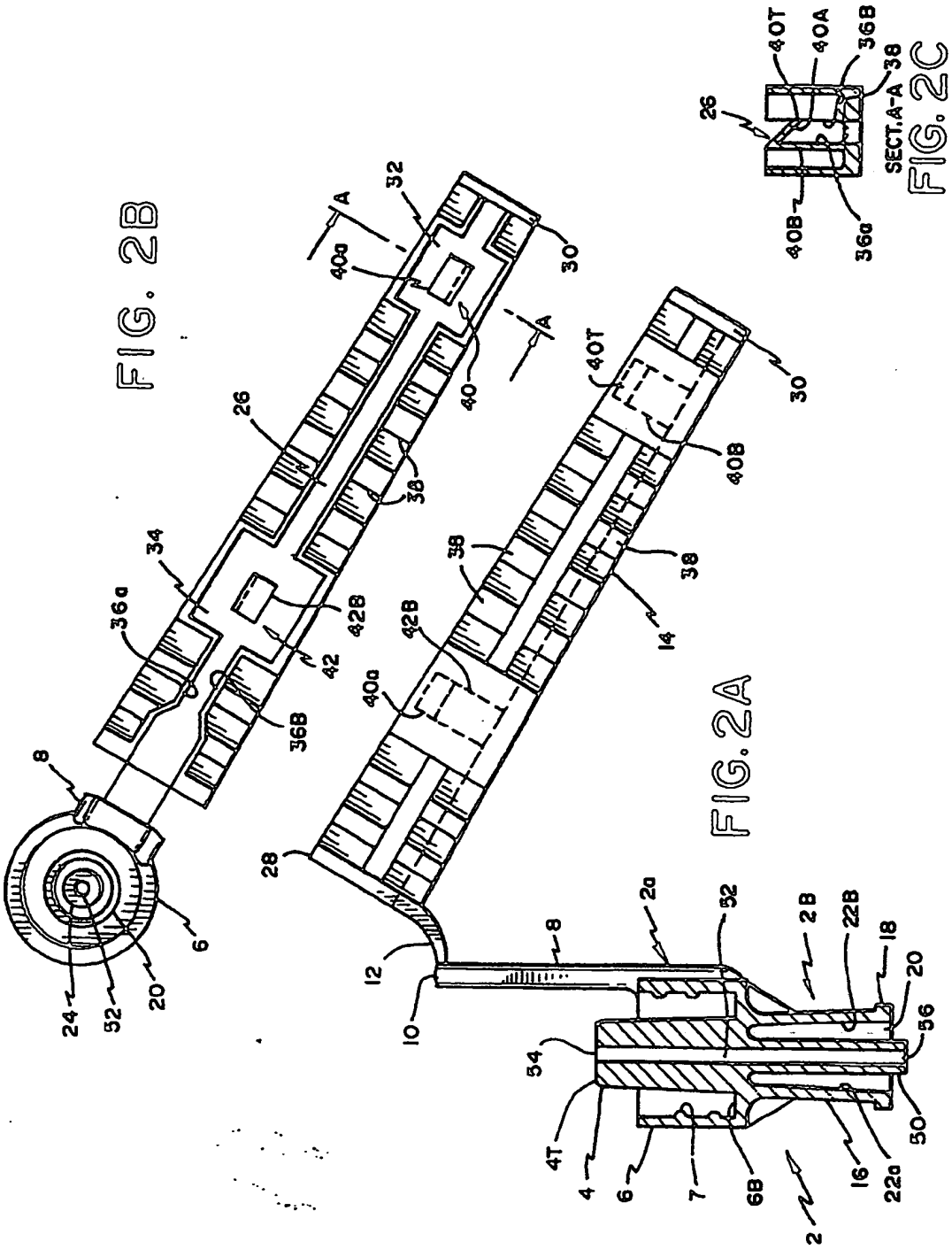
FIG. 2B
FIG. 2A
FIG. 2C
SECT. A-A
A
32
30
40a
40
26
38
34
36a
42B
42
36B
8
6
24
52
20
40T
40A
36B
38
26
40B
36a
28
12
10
8
2a
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2B
22B
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20
56
54
50
4T
4
6
7
6B
16
22a
2

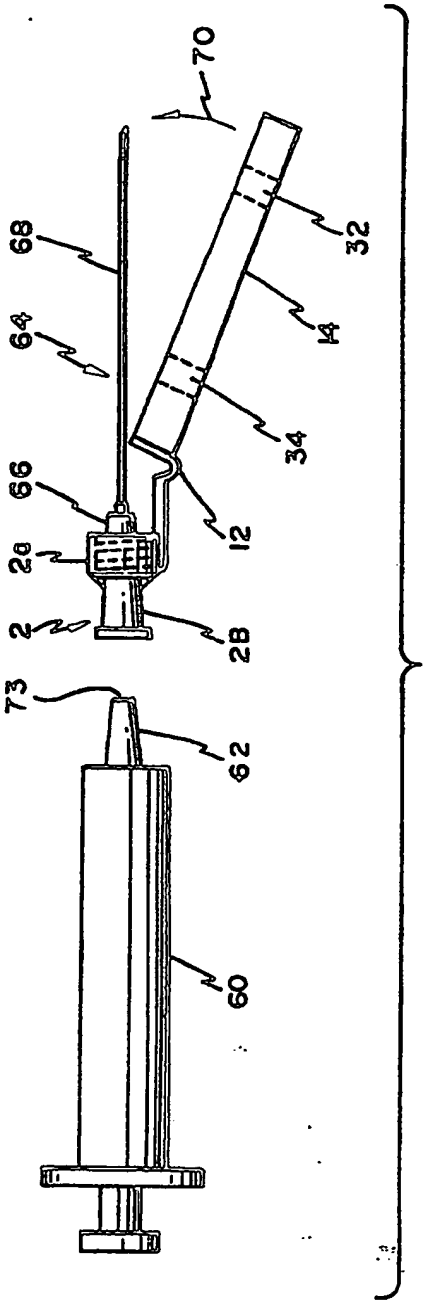
70
68
64
66
20
2
32
14
34
12
28
73
62
60

FIG. 3

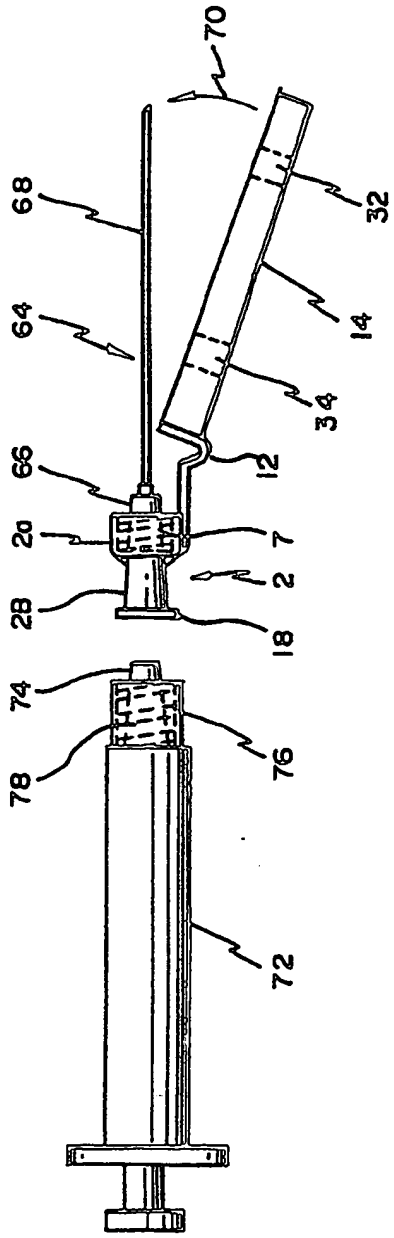
70
68
64
66
20
28
32
14
34
12
7
2
18
74
78
76
72

FIG. 4

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 91 30 4501

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y,D	US-A-4 820 277 (MORELLI) * abstract; figures 4-10 * * column 4, last paragraph * * column 5, line 47 - line 60 *	1-4,6, 9-11	A61M5/32
Y	US-A-3 707 162 (THURECHT ET AL.) * abstract; claims; figures *	1-4,6, 9-11	
A,D	US-A-4 872 552 (UNGER) * abstract; figures *	1-11	
A	EP-A-343 438 (BECTON DICKINSON & CO) * abstract; figures *	1-11	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	02 AUGUST 1991	MIR Y GUILLEN V.

CATEGORY OF CITED DOCUMENTS

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